IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,	)	**Civil Action**
Plaintiffs,	)	
v.	)	
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,	)	
Defendants.	)	**No. 12-1032-GMS**

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Wilmington, Delaware
Monday, July 14, 2014
9:30 a.m.
Markman Hearing

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

RICHARD D. KIRK, ESQ., and
STEPHEN B. BRAUERMAN, ESQ.
Bayard, P.A.
-and-
MATTHEW R. FORD, ESQ.,
SUNDEEP K. (R0B) ADDY, ESQ., (Denver, CO), and
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APPEARANCES CONTINUED:

STEVEN J. BALICK, ESQ.
Ashby & Geddes
-and-
ERIC R. SONNENSCHEIN, ESQ., and
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Counsel for Defendants

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THE COURT: Good morning. Please, take your seats.

(Counsel respond "Good morning.")

THE COURT: We will wait a few moments and see if GSA does anything about the temperature of the courtroom. Let's start with introductions.

MR. KIRK: Good morning, Your Honor. Richard Kirk from Bayard. My partner Stephen Brauerman joins me. We are joined by our partners from Bartlit Beck Herman Palenchar & Scoot Matthew Ford, who I think will be the chief presenter, Andrew MacNally, and Rob Addy.

We are also joined by Bayer's representative, the chief patent counsel for Bayer Health, Aseem Mehta.

THE COURT: Mr. Lind didn't want to make the trip?

MR. FORD: No, he couldn't make it today.

MR. BALICK: Good morning, Your Honor.

THE COURT: Good morning.

MR. BALICK: Steven Balick from Ashby & Geddes on behalf today. I am joined from the Covington & Burling firm by Eric Sonnenschein and Jeremy Cobb. Also, Thomas Poce from the company. And we have a technician with us this morning, Kurt Evans.

THE COURT: All right.

Counsel, I have a letter from Mr. Kirk. Is this agreed, this way of proceeding?

MR. SONNENSCHEIN: Yes.

MR. FORD: It is.

THE COURT: Okay.

MR. FORD: Thank you, Your Honor. Your Honor, I have a copy of the PowerPoint that I am giving.

THE COURT: You might want to pass up one for my court reporter as well.

MR. FORD: Your Honor, as you know, the parties have agreed to the order set forth in the letter. Of course, if you ever want to deviate from that, please, let us know.

THE COURT: I don't need an invitation for that, counsel.

MR. FORD: I have a PowerPoint presentation set up. I am happy to proceed with the PowerPoint. Again, if you want to talk about a different area, we can talk about

wherever the Court wants to go.

What I would like to start with is, if it is all right with the Court, on the claims at issue here or the claims that we are asking the Court to construe.

Your Honor, I put on this white board here the claim broken down by, essentially by clauses, more or less. Given my height, I can only refer to some part of it. Eric can probably get to higher parts of it. But I want to give you an overview of what is claimed here.

It is a contraceptive regimen that first has a first and second hormone component. And the first hormone component contains two pieces, a progestin and an estrogen. We are going to be discussing the estrogen a good deal today. But both are part of the contraception regimen.

The second hormone component consists essentially of an estrogen, one of the two ingredients that is in the combined pill, as well as placebo pills that are between these two hormone components, such that the total cycle, when you put all these pills together, it is at least 28 days.

What we are discussing today is this last part, which the parties have been referring to as the "whereby" clause. I think both of us have been using it somewhat specifically to refer to the last portion of the whereby clause, which really is the direct object of the clause

itself.

So in full, the clause reads, "...whereby the low effective estrogen content" -- this is a term for construction -- "and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side effects."

So those are the terms that we have before you.

A first dispute between the parties is what to make of this portion of the whereby clause, whether it is a single limitation, which is what Bayer proposes, or whether it is a series of individual limitations, which is Warner Chilcott's position.

Your Honor, there are three reasons why you should adopt Bayer's construction, at least at the outset, with respect to this being a profile.

The first is that that is what the claim language indicates. That is what is indicated in the prosecution history. And that's what would be indicated to a person of ordinary skill in the art based on contraceptive science.

The second reason is that the remaining terms, the characteristics that are here, have an understood and known meaning to a person of skill in the art. Each of

these characteristics is a known characteristic in the art when assessing a profile for an oral contraceptive. And each of these terms is a way of characterizing the clinical assessment of whether an oral contraceptive achieves these five characteristics.

They make this determination, a person of ordinary skill in the art, based on a comparison to healthy women who aren't otherwise on hormonal contraception. In essence, that means that when you are testing an oral contraceptive to see what it does, you compare it against a population of healthy women.

The last reason is that the comparisons proposed by Warner Chilcott both cannot reasonably be done, meaning a person of ordinary skill in the art cannot reasonably make the comparisons that they are asking, and a person of ordinary skill in the art would not make the comparisons that they are asking.

Those are the three reasons that I would like to go through here in greater depth.

We discussed that there is a progestin and an estrogen that make up an oral contraceptive. What does it mean when Bayer says that this whereby clause claims a profile as opposed to a list of seriatim limitations? Well, it means that the components interact. It means that high contraceptive reliability, low incidence of follicular

development, et cetera, they are interrelated, and you cannot have an instance in which you are the greatest at all of them, because in order to create the profile, tradeoffs have to be made.

The five effects that are listed here, the characteristics that are listed here, are identified in the patent as among the three areas of points of emphasis when developing a contraceptive. These are known points of emphasis in the art when someone, a person of skill in the art, develops an oral contraceptive.

I mentioned that there requires balancing. The regimen itself obviously contains more than just estrogen. But the estrogen component requires making certain tradeoffs. And this is holding all else constant, and, of course, there is more to it in the claim, but as you increase the estrogen amount, generally, you are going to have better cycle control. We will go through what cycle control is. But it is dose-dependent. You have better cycle control with higher estrogen content.

That also includes intracyclic menstrual bleeding. The higher it is, the better profile you are going to have.

Likewise, you are going to have a higher incidence of undesirable side effects, because many of the side effects in an oral contraceptive are related to the

estrogen component, and they are dose-dependent.

Likewise, when you lower the estrogen amount, you are going to affect the cycle control. You may have higher incidence of intracyclic bleeding, you may have worse cycle control. And you are going to have a lower incidence of side effects. This is the tradeoff that occurs in balancing these characteristics when designing an oral contraceptive.

What Bayer claimed was, here it's just indicating the estrogen amount, but a regimen in which there is a low effective estrogen content, low total hormonal content, that produces this profile here. That is the contraceptive. That is what is communicated and conveyed in the whereby clause itself: a set of interacting characteristics that Bayer achieves through the regimen as claimed in the preceding portions.

To say that it is not a profile and accept Warner Chilcott's articulation of it would be to take this interactivity apart and to say that you could have a regimen that has the highest contraceptive reliability, the best cycle control, the lowest incidence of intracyclic menstrual bleeding, lowest incidence of side effects than existed in the prior art, you can divorce this interactivity and create a regimen that can function as being the first horse in every race. We will go through why that is not a plausible

reading of the claims to a person of ordinary skill in the art.

But what is clear is that in order to get that construction, Warner Chilcott has to show that Bayer disavowed the claim scope. By claim disavowal here in this context, that means that Bayer said, essentially, that although high contraceptive reliability is there, not highest, that when Bayer wrote high contraceptive reliability it meant that theretofore, before this time, no one had achieved high contraceptive reliability. That is claim disavowal and has a very strict standard.

The case that governs -- I know this Court knows this from the briefs --

THE COURT: Then why go through it, if you know it?

MR. FORD: That's a good point. Just to point the Court to the standards --

THE COURT: For claim disavowal?

MR. FORD: For claim disavowal.

THE COURT: I am acutely aware of that. Go on.

MR. FORD: I am happy to move on.

THE COURT: I suggest that you do.

MR. FORD: Thank you.

Within the prosecution history, we have the addition of the whereby clause that occurs as part of an

amendment over a rejection by two prior art references, Pasquale and Ehrlich.

In stating that the whereby clause was novel, the regimen was novel, Bayer did not say that it had achieved for the first time the highest contraceptive reliability or high contraceptive reliability. What it said was, as set forth in the prosecution history and set forth here, was that it had achieved this profile by using a low effective estrogen content and low total hormonal content as set forth in the regimen, and that these results, there is no suggestion in either of the references here, Pasquale and Ehrlich, that these results could be achieved as set forth in the claim.

In their brief, a number of times Warner Chilcott says that Bayer had said we achieved high contraceptive reliability for the first time or satisfactory cycle control for the first time. That is a misreading of the prosecution history. The sentence that they are relying on here does say "for the first time," but it's referring to, again, the previous sentence that teaches that no one had taught the use of this amount of estrogen in this regimen in order to achieve the results contained in the whereby clause. And it says that these results are what have yet to be achieved in the art, not that it has achieved for the first time high contraceptive reliability.

Also, in the specification, Bayer does describe disadvantages of the prior art. Here is one with respect to Mercilon discussed in the briefs. Here is one with respect to Pasquale, which was in the prosecution history, also discussed in the briefs, noting that there are shortcomings in the art.

And here is a section in Column 6 in which the patent discusses the advantages of the regimen but does not say, for example, that although there is a significantly lower frequency of follicular development in the user, that all of the prior regimens have a high incidence of follicular development. It is not disavowing the scope of what had come before.

In addition, if you look here in the prefatory paragraph to this series, it's discussing a number of different regimens, some of which are, generally, 28 days, some of which have seven estrogen days at the beginning of the regimen, some of which have seven placebo days, some of which have 30 micrograms of ethinyl estradiol. As we saw, because there are dose dependencies here, there is not a single comparison that is made or that could be made with respect to the profile and all that came before it.

The Court knows, again, claim disavowal, what I would like to do is point out here a specific example in Ventana Medical Systems case as to why these types of

statements aren't enough. In Ventana, the patent said it was more rapid, more reliable, more reproducible than standard methods. And the Court said that is not enough. These general statements, without more, that is not enough to get claim disavowal under the patent background here, except that Warner Chilcott is saying we said it was the best. These are statements that fall short under claim disavowal and would not be sufficient.

As a result, because this is a profile, it can't be viewed seriatim as Warner Chilcott proposes. Instead, you have to view each of these limitations in context, each of them as part of the context of the larger profile.

What I would like to do is just move on to Warner Chilcott's proposed construction, and why, if you divorce it from the idea that you are balancing and creating a profile with respective to the contraceptive, why it requires the impossible, because when we have an estrogen-dependent dose that produces different effects for different aspects of the profile, what Warner Chilcott is saying is that we have to produce the highest contraceptive reliability, the best cycle control, the lowest incidence of intracyclic menstrual bleeding, and the lowest incidence of side effects, while using the lowest effective estrogen content.

The prior art, as stated in the patent, a person

of ordinary skill knows that these regimens contain much more estrogen, for example. And they know that the dose response is proportionate with respect to these characteristics. And a person would not read that profile and read this and say that Bayer had claimed to teach the highest or the best or the lowest incidence, when it knows that Bayer is claiming a low effective estrogen content and when it knows that these are generally dose-dependent.

This is set forth in fairly succinct language in Warner Chilcott's invalidity contentions, where they say, assume our constructions are correct. A person of ordinary skill in the art would read that and say, that's impossible, there is no way that you can do this, for the exact reasons we have discussed, because we have other doses of estrogen in the regimens that are higher, 30 micrograms or even 40 micrograms. And because that is impossible, as Warner Chilcott says in its invalidity contentions -- maybe not exactly impossible but unbelievable -- it means that the construction is wrong. A construction that divorces this from the profile and requires superior performance in every category can't be right, because a person would look at it and say it's impossible given what's in the prior art, based on the comparison of Warner Chilcott.

That is with respect to the profile.

What I would like to do now, what we have agreed

to do now -- correct me if you have a different understanding -- is go through each individual element and discuss the constructions here in this whereby clause.

THE COURT: Yes. That is what I understand is proposed.

MR. FORD: Starting first with "high contraceptive reliability" here, this slide just sets forth the dispute. Really, there are two or perhaps three disputes. The first is whether high contraceptive reliability has meaning in the art, whether that is a known term in the art. The second is whether the Pearl Index is what should be used in order to measure contraceptive reliability for purposes of a comparison to the regimens in the '940 patent.

So for the reasons I have just discussed with respect to the whereby clause and viewing it as a profile, we don't think this type of comparison to the prior art regimens is proper because it essentially is claim disavowal. They haven't met the standard there. We would also like to go through why in this instance, with respect to contraceptive reliability, it is not the right reading.

The intrinsic evidence uses the phrase "high contraceptive reliability," "high contraceptive effectiveness," without any type of definition whatsoever. It is a clinical assessment with respect to the performance

of a contraceptive. And there are known methods in the art for measuring the effectiveness of the contraceptive.

The extrinsic evidence uses the same type of characterizations when discussing oral contraceptive regimens, saying that they have --

THE COURT: Let me ask both of you, because I see extrinsic evidence on the screen, and I have competing affidavits from physicians, I believe. Is it your thinking that I need this extrinsic evidence to understand the technology to enable me to perform my task of deciding the disputes?

As you both know, I generally don't get into truth-swearing between experts in the extrinsic arena. At least I won't do it until the next term of the Supreme Court maybe tells us we have a new standard, hopefully, that is going to recognize that trial judges are doing fact-finding and get judged by the "clear error" or some type of standard.

That is my rant for the day about the Fed Circuit.

I would like an answer. Why are we going here?

MR. FORD: Can I ask to clarify? Are you saying extrinsic evidence generally or the expert reports in particular?

THE COURT: Expert reports are part of an

extrinsic regime.

MR. FORD: I understand.

Our position is that the expert reports themselves are of little use.

THE COURT: What is this?

MR. FORD: This is extrinsic evidence. These are treatises. And I understand it's extrinsic evidence.

THE COURT: This is a treatise.

MR. FORD: These are treatises, yes, Your Honor.

THE COURT: I just wasn't sure, given that I had seen affidavits, and, I think, probably in this rather extensive appendix, references to deposition testimony and things of that nature, where we were going with this, because it is not clear from me from looking at the screen the source of this particular slide.

MR. FORD: That is a fair point, Your Honor. For purposes of indicating -- A, these are cited in the brief. B, these are sourced below each quote.

For example, we have the European patent application cited there, an article by Killick on fertility and sterility to the right, and on the bottom right we have an article by Serfaty.

THE COURT: These are peer-reviewed articles?

MR. FORD: The two on the right are peer-reviewed. The top left is a patent --

THE COURT: We are not talking about treatises. I thought you were going to dictionaries. Counsel, I need a clear answer to my question. Where are we going with this extrinsic presentation? I don't have a clear understanding.

MR. FORD: That is fine. Our position is the meaning is clear from the text of the claim itself, and that it will be understood by a person of skill in the art. All this is meant to show --

THE COURT: If you could tell me why I should deviate from the teachings of Vitronics, I will do that. I give counsel all the time the opportunity to do that. Invariably, you don't. But if I need this to help me do my job, please, tell me why I need it. That's all I am saying.

MR. FORD: It is simply meant to provide the context of these --

THE COURT: I don't need context, unless you are helping me understand meaning and thereby giving you meaning and thereby giving the jury meaning. Otherwise, I am not going waste my time with extrinsic evidence.

MR. FORD: I understand, Your Honor. To the extent that it is providing -- fair enough. I understand.

THE COURT: Counsel, I don't mean to hamstring you in your presentation. If this is a linchpin of what you need to do, go right ahead and do it, and I know how to ignore it if I don't need to use it. Why don't I let you do

what you feel you need to do. And I will do, back in the confines of my chambers, what I must. Let's just go.

MR. FORD: I certainly don't want to waste your time.

THE COURT: It's really your time.

MR. FORD: I agree.

Before leaving this -- I am not arguing with you as to -- I am explaining what it is, where I am coming from.

THE COURT: I understand. I have invited you to proceed forward. Accept the invitation. Go forward.

MR. FORD: The Court's views are clear, and the intent here is to help to provide meaning to understand what is understood.

THE COURT: I will take it in that spirit.

MR. FORD: Thank you, Your Honor.

Again, along the same lines, with the Court's admonition in mind, we have here characterizations of contraceptive efficacy in time. These are clinical assessments. A high contraceptive reliability assessment is a clinical assessment made by people of skill in the art with the known methods for assessing clinical reliability and the ability to reach conclusions as to what is high for purposes of contraceptive reliability.

That is what is intended to be shown here. Warner Chilcott says itself, Promotes lower estrogen having

a high level of effectiveness. And it says, Clinical development agrees that as far as they are concerned, the FDA's criteria for approval for safety and efficacy is very similar across all contraceptives that are presented.

What I would like to do here is briefly address the Pearl Index, which is the portion of Warner Chilcott's construction that they ask the Court to adopt.

The Pearl Index is not in the patent. It's not in the prosecution history. It's not in the prior art.

I would briefly just like to explain what the Pearl Index is so you have a sense of it. This is just an iconographic example where we have a hundred women. It is one method of measuring the effectiveness of an oral contraceptive. We have the measuring of the Pearl Index as the number of pregnancies for a hundred years of women use. What that means is if we have a hundred women studied for ten menstrual cycles with two pregnancies during the cycle indicated here, the Pearl Index would be calculated using this formula, and we get a 2.6 index.

The math is not as important as the variables, the information that is contained within the Pearl Index or needed to calculate the Pearl Index. That is the number of pregnancies, because that is what it measures. It is the number of women studied, it is the number of cycles studied.

None of that information, the Pearl Index is not

in the '940 patent, none of this information is in the '940 patent.

The Pearl Index we don't dispute in the art as a basis for assessing pregnancy. There is no dispute there. It is just not the classical first term, anyway, whether something is -- there is no numeric value of the Pearl Index that says high versus not high. That is not in the art. In particular, there is no ability to calculate the Pearl Index and compare it to what's common in the prior art regimens, because the same information is missing from the prior art.

So to the extent that Warner Chilcott's construction asks the person of skill to compare Pearl Indices, the information just isn't there. Assuming that the information even is there, at the time a person of skill in the art would not do that comparison because you cannot compare Pearl Indices across studies of different clinical studies. The reason is that there are differences among those studies that make comparison very difficult to do.

You can establish comparability. Generally, it requires assessment. But what you can't do is say I have Pearl Index A and Pearl Index B, A is greater than B, therefore, B is a better contraceptive. It is not a type of comparison that can be made. That was known at the time in terms of how Pearl Indices would be used or not used in this instance. And that is true today from their own expert, who

says that you can't do that type of comparison.

Does Your Honor have any questions about high contraceptive reliability? Otherwise, I can keep trucking.

THE COURT: Keep trucking, please.

MR. FORD: The next term is "satisfactory cycle control" and "intracyclic menstrual bleeding." I am treating both of these together.

As the Court knows, the constructions, Warner Chilcott's proposed construction for both is very similar if not identical. It makes sense to treat it the same.

The first question is whether cycle control means incidence of intracyclic menstrual bleeding or whether it means something else. The second question is back to our comparison, who do we compare.

The specification itself, in terms of the cycle control, is not interested with menstrual bleeding, because although it does say at the beginning here "good cycle control, i.e., low incidence of intracyclic menstrual bleeding," elsewhere it discusses the fact that cycle control includes breakthrough bleeding, which is withdrawal bleeding.

I will give the Court some sense of what that means in a few minutes. But the patent itself does not equate cycle control with intracyclic menstrual bleeding, as is done in Warner Chilcott's proposed construction.

"Cycle control" itself is used without any need to further define it apart from what is here.

The intrinsic evidence confirms this as well. The two patents, Oettel and Ehrlich, which say here is a perfect cycle control while possibly preventing intermenstrual bleeding, again, that's the same concept, there is a difference between the two. Here we have Ehrlich saying cycle control, i.e., regular withdrawal menses with optimally few intermenses.

What that is saying optimally few intermenses, which is intracyclic menstrual bleeding, with also regular withdrawal menses. So there are these two components to it as set forth in the intrinsic evidence.

THE COURT: These are some of the deficiencies in the prior art that you are pointing out?

MR. FORD: No. I am sorry, Your Honor. We have two pages of prior art that are cited in the patent specification itself.

THE COURT: I guess one of the questions I have is what are the deficiencies in the prior art, as discussed in the prior art?

MR. FORD: The deficiencies in the prior art, there are, generally -- I can put the patent up if you want to take a look at it.

THE COURT: Sure.

MR. FORD: To make it easier, I can go back to the slides to show you.

THE COURT: You can tell you me. I have the patent in front of me.

MR. FORD: First, you could look at -- there are three general areas. The first is at 2, from 55 to 67, Column 2. That discusses an oral contraceptive, Mercilon. And Mercilon was a low-dose oral contraceptive with a 21/7 regimen. And the statement here, the criticism here of this was that the cycle control was somewhat less good than preparations with a higher estrogen dose, and that there was slighter ovarian suppression for a preparation containing 20 micrograms of ethinyl estradiol, and that was a clinically important problem.

So an identification of a problem isn't necessarily saying that the patent is superior. But it's an identification of the problem.

Also, at Column 3, 25 through 40, there is a discussion of a number of different regimens. And this includes, I believe it's pronounce "cool," Kuhl, and Pasquale, which is the reference discussed in the prosecution history. There, these regimens began with a low dose of estrogen. And the dose of estrogen was not itself sufficient to inhibit ovulation. So if you start with a low dose of estrogen, there is a risk that the menstrual cycle

will kick off at that period of time because there isn't enough hormone to stop it.

The criticism here is that in these regimens, follicular development can start to occur in this early period when you have lower doses of estrogen than are set forth.

Again, it says that contraceptive protection is thus jeopardized and risk of pregnancy is high, especially in the incidence with the low dose if you have the estrogen first.

Again, this is something that was different from the regimen that is claimed here, where you begin with 24 days of a combined oral contraceptive pill that is contraceptively effective.

Column 6 is where the advantages of the patent are set forth and discussed with respect to regimens, here, the regimens that are in the art. It states here that -- again, we discussed this earlier -- but these are a host of regimens in which a person of skill in the art wouldn't expect, one, a low-dose pill to perform better than, for example, a 30-microgram ethinyl estradiol pill. We saw that in the earlier slides. And in Column 6 here we have a discussion of what are called the advantages of this combination. They are discussed in a very general sense. Nowhere here does the patent say that the patent cures all

this, that the patent makes all this go away or that there was anything wrong with the prior art with respect to performance until the regimen came along.

What the patent does is claims a contraceptive profile, as I said earlier, that can be achieved. It doesn't say it's the only one that has high contraceptive reliability. But it does. And it does in the context of having all of these effects, which are as set forth in the patent, parts of the three points of emphasis for a particular development of an oral contraceptive.

THE COURT: Thank you.

MR. FORD: Returning to cycle control, this is intrinsic evidence, what I mean by that is patents that are cited on the face of the patent, we have cycle control having a known meaning here. Again, not something that is defined. A person of skill in the art knows what cycle control is. And we discussed earlier that it is broader than just intracyclic menstrual bleeding.

The intrinsic evidence also demonstrates -- these are two patents -- that satisfactory cycle control is a known characterization. These patents have shared inventors with other patents, but these terms are used, and they were never discussed as being unclear or as something that wouldn't be understood by those of skill in the art.

I know the Court gives little weight to it. But

others use this term. Others characterize cycle control as being acceptable.

There are clinical methods for assessing cycle control. What it is is measuring the same things we just discussed, intracyclic menstrual bleeding and the reliability of the withdrawal bleeding, whether it looks like the typical menstrual cycle.

People of skill in the art and in extrinsic evidence, as well as in treatises, are able to say, as well as in peer-reviewed published literature, are able to describe cycle control as satisfactory. It is not a characterization that causes any type of issue.

To the extent the Court is inclined to rely on expert testimony, I can discuss this. To the extent the Court isn't, I can move on.

THE COURT: I am really not inclined to rely on expert testimony, unless you tell me why I should.

MR. FORD: It is our position you don't. The point of these slides, which I will skip, is to show that there is good reason not to use what Dr. Simon is saying in his a rebuttal report, as it is inconsistent with what he said elsewhere.

THE COURT: For your edification, there is no one formula for doing this, we all know this. You are experienced patent lawyers. But until there is some word to

the firmament in terms of how we review, I have too many cases -- I have colleagues who sit down, and I appear on panels regularly, Stan Chester in New Jersey, and he routinely hears from experts on the witness stand. I don't have time for that. He has a lot more fewer cases than I do. And he enjoys it. I don't. Just to help your thinking.

MR. FORD: I absolutely appreciate that. Our position is you don't need these reports, either.

THE COURT: Then let's move on.

MR. FORD: I will keep trucking.

That let's skip a number of slides here.

Here we have again, the intrinsic evidence, this is Ehrlich and Oettel, the '242 at the bottom, both of them are cited on the face of the patent. The discussion here is at, I believe, at 2-6 to 24 in Ehrlich, which states that in this instance, a 21-7 regimen, the seven-day pause has a withdrawal bleeding that simulates the natural menses. That is the purpose of the withdrawal bleeding, again, simulating the natural menses. Similar language is contained in the '242 patent.

And, of course, as stated in the brief -- but again, the Court may not give much credence to it -- their expert agrees in litigation over this same product.

Now, the construction here, moving to

intracyclic menstrual bleeding, treating these as the same because we have the same construction by Warner Chilcott, if you look -- really, the only dispute here, both terms use intracyclic menstrual bleeding, the question is whether to add that parenthetical at the end that says, "i.e. any bleeding occurring outside the hormone-free interval."

Just very briefly, to explain why that parentheses is wrong, the typical menstrual cycle is punctuated by menstruation. It is pretty straightforward. When you have a traditional 21/7 regimen, as we saw in the intrinsic evidence, you have a withdrawal bleed that occurs at the end. And that's not the same as menstruation. It's just the body's reaction to not having hormone anymore. But for reasons of more anthropology than anything else, it was meant to confirm that a woman wasn't pregnant and it occurred. The idea was to create for a 21/7 regimen this withdrawal bleed that mimics natural menstruation.

Warner Chilcott's construction says that any bleeding occurring outside the hormone-free interval is intracyclic menstrual bleeding. That might be fine for a 21/7 regimen. It's not for what we have claimed here, because what you have is, in the specification here at Column 4, 28 through 35, you have a discussion that the combination of having a placebo pill -- two placebo pills and having two low-estrogen-dose pills results in this

withdrawal bleeding.

So a woman can be bleeding during the two days of estrogen-only pills and not be having intracyclic menstrual bleeding. So that's why the parentheses that is there and saying that it occurs outside the hormone-free interval is not correct, because you can still have bleeding when you are taking hormones in the estrogen patents.

Now, the patent itself, this applies to both cycle control and intracyclic menstrual bleeding, their constructions, the comparison can't be done that they are asking the Court to make. The rate, for example, they are saying the incidence of intracyclic menstrual bleeding isn't set out in the patent with respect to this regimen. It's not set out in any of the prior art regimens that would have to be compared.

Again, this is extrinsic evidence that the Court will likely ignore, you can't compare cycle controls between two studies. The same way with the Pearl Indices, you can't compare Pearl Indices. There is no way to say a study was performed here, has a lower incidence, and I can therefore compare it directly to another person of skill in the art, this is their expert in another case, says you can't do that comparison with data from different clinical studies even if we did have the data available to us.

Does the Court have any questions about these

terms?

THE COURT: I do not.

MR. FORD: Moving to "lower incidence of follicular development."

Follicular development, I know Warner Chilcott reserves the right to say that it is indefinite in a footnote, which we have no issue with. We just know it's not before the Court on construction. I say we have no issue. Of course, we dispute it.

For purposes of construction but not wanting to put words into Warner Chilcott's mouth, we are not asking the Court to construe that term. The question is whether the comparison is to a population of healthy women or whether it is to every contraceptive regimen in the prior art.

Here in the '940 patent at 7, we have the known methods, two methods for assessing the follicular growth. Those consist of ultrasound, which measure the size of follicles, and the hormone studies, which measure essentially the menstrual cycles, the hormonal fluctuation in the menstrual cycle and whether it is resulting in follicular development.

The patent itself, again, at Column 7, relates the degree of follicular development to the normal menstrual cycle by saying that we have, whether the usual number of 21

days to 23 or 24, by moving it above 21, it is a shortening of the pill-free interval, which is when the selection of follicles occurs with conventional combination preparations as in a normal menstrual cycle.

So it is relating the follicular development that is occurring here to the normal follicular development that occurs during the menstrual cycle, and also at Column 7, saying that follicular development is responsible for breakthrough ovulations.

So it is again relating the degree of suppression or inhibition of follicular development to what would occur in a normal menstrual cycle.

THE COURT: Looking at Column 6, I think starting at Line 7, I think Warner Chilcott is arguing that claims like this in the patent and specification support their position on the meaning of this term. After the colon?

MR. FORD: Column 6, Line 7?

THE COURT: Whatever line it is. The paragraph that is enumerated 1, Significantly lower frequency of follicular development.

MR. FORD: That's right, Your Honor, yes.

THE COURT: That language is there. What does it mean in terms of your position vis-a-vis Warner Chilcott and their proposed definition?

MR. FORD: Our position is the term itself is low incidence of follicular development. That is in the claim. That would be understood to a person of ordinary skill in the art. That is our position. And assessing whether something is a low incidence is something that they are able to do.

Looking at the patent and the lines that you pointed out, what it says is that with respect to an unidentified regimen, the patent itself kind of lumps together a number of different regimens in which there would be different amounts of follicular inhibition, depending on the amount of estrogen, lumps them all together; says there that with this regimen that is a lower frequency of follicular development. What Warner Chilcott says that means is that we claim the lowest, that we are lower than every single regimen that comes before.

Our position is that the claim itself does not say lowest. The claim says "low incidence."

The fact that this follicular development may have occurred before doesn't mean that before there was no low incidence of follicular development in prior art regimens.

That is the divide vis-a-vis that section right there.

Does that answer your question?

THE COURT: Well, let's look at the paragraph. It says, "The advantages of this combination, preparation," there is a parenthetic, "(according to the invention) that is administered generally over 28 days compared to previously described preparations," then it goes on to list the advantages. One is a "significantly lower frequency of follicular development."

Warner Chilcott proposes, defendant proposes a lesser incidence of follicular development than the incidence of follicular development contained in the prior art.

Maybe that is the difficulty we have, "contained in the prior art."

MR. FORD: Exactly. That paragraph, it is dose-dependent. You have a number of different regimens that are lumped in here together, some of which have much higher amounts of estrogen than does the claim regimen. And a person of skill is not going to look at that and say that something that is stated in the claim, we would say even should be lower, 15 micrograms or less than 20, is going to achieve a great improvement in follicular development over 30 or even 40-microgram estrogen development. In particular, in the discussion of follicular development here in the patent, when it is stated more explicitly with respect to prior regimens, it concerns Pasquale and regimens

that begin with low doses of estrogen and go on and allow for follicular development to occur right at the outset. And so one issue with just saying that each and every prior art regimen is these are very different regimens that are going to have very different profiles. And a person of skill in the art is not going to look at this and think that it is better in every way than all these very different regimens, because they have different impacts. They have different estrogen doses, different impacts.

THE COURT: Okay.

MR. FORD: And a person of skill in the art, again, would have a method using the same methods that are set forth in the patent itself, this measurement of follicular development as well as the hormone levels that occur, the ability to conduct clinical studies and to evaluate the degree of follicular growth and to assess it, to make the exact same assessment that is here, low incidence of follicular development, using the same methods that are set forth in comparison to the normal menstrual cycle and the amount of the follicular growth that occurs while taking the contraceptive versus what would happen without the contraceptive.

Again, based on what's in the Warner Chilcott proposed construction, another issue that we want to flag for the Court is that the comparison again cannot be made

that they ask, cannot reasonably be made. The incidence of follicular development is again not in the patent. There is no set forth incidence. The incidence of follicular development is not set forth in the prior art.

There is no basis for saying that a person of skill in the art could just look at the patent and look at the prior art and therefore know one is greater than the other without conducting clinical trials comparing the two.

The data just isn't there to make the comparison that they want. Whereas there are known methods in the art as described in the patent for assessing follicular development.

Moving on to side effects.

Again, setting up the dispute for the Court, we don't ask, subject to any clarification of Warner Chilcott, we don't ask the Court to construe "undesirable side effects." The question is whether the comparison should be between a healthy woman or should be all prior art regimens. That is the issue again.

It is stated in the patent, a point of emphasis again is to minimize undesirable side effects.

The side effects occurring generally in oral contraceptives, I think of them in two different categories. One is a side effect from taking a pill that comes from having estrogen in your system. Those side effects tend to

mimic pre-menstrual syndrome because during pre-menstrual syndrome a woman has free-floating estrogen in her body and that has side effects. And one of the advantages of oral contraceptives, especially low-dose oral contraceptives, is that you can get much less estrogen, a woman has less estrogen floating in her body, and therefore those estrogen-related side effects are lower.

This is set forth in Column 6, Line 33 to 38, where the combination dosage set forth here improves cyclic control, lowering incidence of side effects, such as headaches, within the framework of the pre-menstrual syndrome. That is discussing, again, these types of estrogen-related side effects.

Above that we have a discussion from Column 1 where a particular type of side effect associated with side effects and estrogen is listed, and that is cardiovascular disease. Again, the person of skill in the art, when they are conducting these types of studies, evaluating whether there is an amount of side effects, they are going to compare that to the baseline.

Bayer's position is not that a woman that is not taking hormonal contraceptive has side effects. Bayer's position is simply that if you are assessing the side effects, assessing the profile of a contraceptive, you are going to examine that based on what it is the contraceptive

is doing in light of what would happen if you didn't take the contraceptive. This is known in the art. This is how studies are done, comparing and assessing the degree of extrinsic evidence. There are studies cited in the briefs that you can look at.

Again, going back to the comparison Warner Chilcott asked the Court to make -- again, we are on the same issue -- where this data does not appear in the patent itself, although side effects appear, those of skill in the art are able to assess them. There is no data in the patent and there is no data in the prior art with respect to the incidence of side effects that would be compared.

In fact, again, Lo Loestrin's own labeling from today says you can't compare incidence of side effects across different clinical studies, which is the same comparison which they are asking the Court to make here.

Any questions with respect to that limitation?

THE COURT: No.

MR. FORD: Okay.

Your Honor, we have discussed what I have called the direct object here in the whereby clause, we have gone from the first to the last.

What I would like to discuss is the "low effective estrogen content," which is part of the whereby clause, although we are treating it separately here.

Up here is just a graphical depiction of the parties' proposed constructions.

Bayer's construction is that it is a daily dose of estrogen equivalent to no more than 40 micrograms of ethinyl estradiol. So it has estrogen content but it is less than 40 micrograms.

Warner Chilcott's construction differs depending on whether it is the combined pill, which is the first hormone component identified in the claim, or whether it is the second pill, which is the estrogen-only component of the claim.

And the difference is that Warner Chilcott allows for much less in the estrogen-only pill, two micrograms/15.

THE COURT: Would less than 15 be effective?

MR. FORD: Yes. Our position is that, yes, it would be.

The patent itself states that low effective estrogen content applies to both that term as it is used in the patent right there in the claim, applies to both sets of pills. And the abstract says that you want estrogen content that is as low as possible in each individual dosage unit. And estrogen content is in two different places here, one in the abstract and one at Column 3.

THE COURT: In the context of this term, the

word "effective" means what?

MR. FORD: In the context of this term, the word effective, in our opinion, the patent itself sets forth a number of different estrogens. This is an estrogen agnostic, this claim. So in order to determine the content of the estrogen, it's looking at the effective estrogen content across the identified estrogens, the synthetic estrogens there.

The low effective estrogen content again applies to both. This is Claim 9, which is not at issue but is useful in understanding the context in Claim 1, where both the combined pill has a low effective estrogen content that is set forth and the estrogen-only pill has a low effective estrogen content that is set forth there. This is a term again that applies to both of these.

The object of the invention -- this is as Column 3, 41 through 43 -- is to have the estrogen content that is as low as possible in each daily dosage unit. The patent is teaching a person of ordinary skill in the art to use as low as possible an amount of estrogen in each daily dosage unit.

The Pasquale patent, again, which is intrinsic evidence, describes 35 micrograms of ethinyl estradiol as being a low dose. The patent itself, at Column 2, 61 through 67, says that 20 micrograms is a very low dose.

The patent itself then, in both the

specification and in the claims, teaches to use even less than that. It says that 20 micrograms is a very low dose, it says using even less than that in terms of the amounts that are identified and claimed here in Claim 9, but also with respect to the effective estrogen content in the estrogen-only pills.

So we have a teaching in the patent, use as low an effective estrogen dose, use as low a dose as possible. The same is saying that 20 micrograms is low, and saying use even less than that.

Those are the teachings. None of those limitations are in this claim, which just says low effective estrogen content.

Now, the problem with Warner Chilcott's proposed construction is that it is essentially limitless. It starts but it doesn't end. The intrinsic evidence says, the Spona '129 patent teaches that the march of history has been to lower the amount of estrogen content in oral contraceptives. Warner Chilcott's proposed construction goes up again very high.

And at the time of the patent itself, there was no marketed oral contraceptive with more than 50 micrograms of ethinyl estradiol, and at least in the opinion of some -- again, this is extrinsic -- that most people should be taking much less than that.

So the issue that ultimately, in our opinion, undermines Warner Chilcott's proposed construction is one of claim differentiation. If there is any difference, Claim 4 of the patent, for example, claims an amount of ethinyl estradiol in the estrogen-only pill as being between 2 and 40 micrograms. And under Bayer's construction there is a difference between effective estrogen content in Claim 1 and the effective estrogen content in Claim 4, because you can have less than 2, you can have, for example, 1 microgram. With their proposed construction, there is no difference between Claim 4 and Claim 1 unless you use a higher amount of estrogen, you use an amount of estrogen that approaches or exceeds the highest amount that has been used in a marketed contraceptive at the time of the invention.

The Court has indicated that you are not considering Dr. Simon, the expert testimony particularly helpful. But, regardless, allowing there to be a -- because of Claim 4 and the limitations in Claim 4, in order for it to have a difference from Claim 1, you have to go to a much higher estrogen amount. That contradicts the patent's teaching to use as low as possible in each amount. It is greater than the amount that we are characterizing as low in the intrinsic evidence, very low in the patent itself. And it is inconsistent with the intrinsic evidence that the march of history describes with regard to the amount of

estrogen.

That is the effective estrogen content. That is everything in the whereby clause.

There is one more claim, which is "between these two hormone components," which is right here.

Bayer's position is essentially this term doesn't need construction. There is a third hormone component in the claim. There is a second hormone component in the claim. And then it says between these two hormone components.

It is pretty straightforward. It would be clear to anyone, a jury, a layperson, to understand identifying two hormone components and saying between. We have offered a construction we think is more straightforward. But we don't think that this term needs construction at all.

THE COURT: Does the specification ever teach that the second hormone component contains anything other than estrogen?

MR. FORD: You are saying the second hormone component?

THE COURT: Yes.

MR. FORD: No. The second is defined as consisting essentially of an estrogen.

THE COURT: Okay.

MR. FORD: Thank you, Your Honor.

THE COURT: Thank you, counsel.

MR. SONNENSCHEIN: Good morning, Your Honor. Eric Sonnenschein for Warner Chilcott.

THE COURT: Good afternoon, Mr. Sonnenschein.

MR. SONNENSCHEIN: I am going to be following the order that Bayer did, with one minor exception. I am going to reverse the very last two terms.

In obtaining the '940 patent, the applicants had to overcome an obviousness rejection. The way that they did that was to add to the claims of the '940 patent the five terms that are listed up on the screen and argue that those terms constituted superior results that distinguished their oral contraceptive from the prior art.

That's how they got the patent. And that's a critical fact that Your Honor should keep in mind when assessing the meaning of these terms.

THE COURT: Counsel, it would help if you talked to me rather than the screen. That should be innate, not your principal means of advocacy. You are an advocate, please.

MR. SONNENSCHEIN: Sure.

Another critical principle that the Court should keep in mind when evaluating the meaning of these terms is that claim terms need to have a definite meaning, and constructions of claim terms need to have a definite

meaning. For constructions to have that, there needs to be an objective way to assess whether an accused product falls within the scope of the claims or not.

It is the Warner Chilcott constructions that adhere to those principles, not the Bayer principles.

As they said, we are going to follow the agenda, with the minor exception that we are reversing these last two terms.

So we will start with the whereby clause as well, as Bayer did, and with the set of five terms that appear within that whereby clause.

Just as an initial matter, we think of these terms as five separate terms, "high contraceptive reliability," "low incidence of follicular development," and so forth. Bayer argues that this is a single term. But these are distinct requirements. They cover different concepts. And they are stated in the conjunctive, meaning that each has to be satisfied. So we don't think it is a serious argument that this is only one term.

Nonetheless, while these are individual terms, I thought I would start with a general discussion of this set of terms, because we believe that the approach that Your Honor should take is the same general analytical approach in deciding all of these.

So as in any claim construction, Your Honor

knows that we start with the language itself. As Your Honor will see, each of these terms contains imprecise language, vague language, "high," "low," "satisfactory," "reliable." These are nowhere close on their own to adequately delineate the scope of the claims.

So we need to go further to figure out whether there is a definite scope to these claims. When Your Honor does that, we would recommend considering a question that Bayer asks in its opening brief and paraphrased up on the screen, the question is: Did Bayer purport to invent an oral contraceptive with a low dose of estrogen that was superior to every prior art oral contraceptive regimen identified in the '940 patent along several different characteristics?

The prosecution history answers that question yes.

I am just going to preview this now. We will come to this in more depth in a little while. They contrasted the deficiencies of the prior art with the superior results of their regimen. And they went on to enumerate what those advantages were. And as Your Honor can see, they enumerated five advantages. And Your Honor will note that these are the very claim terms that Your Honor has to construe. They are equating the terms with superior results.

And they go on later -- and we will look at this in greater depth in a little while -- but they go on to say that their regimen provides these results for the first time in a low-dose regimen. If the prior art had already provided those, it wouldn't have made sense to say that they were providing those effects for the first time.

Now, the specification also says yes. And Your Honor has already looked at this. But to go through, just to recap this, this points out that there are several advantages to their claimed combination preparation compared to the previously described preparations. And this goes on without limitation, without saying that one or more of these advantages may apply; but, rather, giving a blanket statement, an unqualified statement of superiority, that there were several advantages, lower incidence of follicular development, greater contraceptive reliability, lower incidence of side effects, and better cycle control.

These characteristics line up precisely with the characteristics that were claimed as part of the claims of the '940 patent.

So what really happened here? Well, what really happened here was that the applicants drafted their patent. They applied to the Patent Office for a patent. They got a rejection, an obviousness rejection. And essentially what they did was, to overcome that rejection, claimed these

results, claimed these superior results, said, we are better than the prior art and we are better than the prior art in these ways.

So when Your Honor is thinking about how do I construe these vague terms, what standard do I use, we are proposing to use the standard that they were using, one of superior performance, superior performance over the prior art.

And, not to belabor this, but there are two principles that support this approach. One is the Datamize principle. When you have a word of degree or subjective phrase, the Court needs to look to the patent specification or prosecution history for an objective standard. If you don't have that, we don't have a definite meaning.

The only one that is suggested here is this standard of superiority. How do you know that you have these claim characteristics? If you are better than the prior art. That is the standard that was used in the prosecution history. That is the standard that should apply here.

A second principle that supports this approach is disavowal, which Your Honor knows that. But critically, one way of clearly disavowing claim scope is to clearly characterize the invention in a way to try to overcome rejections based on prior art. That is exactly what

happened here. They added these terms to overcome a rejection based on prior art, saying it's these characteristics that distinguish our regimen from the prior art.

Now, Bayer makes a series of arguments about why these should not individually be construed to require superior performance. In their brief, and here today, they say they weren't claiming a combination of superior results. Well, let's look at the claim language and compare that to the prosecution history. It's very clear that they were claiming superior results, not results that the prior art had already achieved.

Your Honor sees that just by lining up the language in the claims with the language that they identified as superior results. They are verbatim.

The second argument that Bayer makes for why we shouldn't construe each of these to require superior performance is this notion that it would be scientifically impossible to achieve multiple superior results. Well, that's completely contradicted, and contradictory to what Bayer said in its patent. It was more than happy when it was applying for the patent to talk about all of these advantages without limitation, to say that they were better in all of these ways and to claim superior performance as a basis for distinguishing their regimen from the prior art.

So what this amounts to is trying to have these things both ways, in prosecution, tout all of these multiple advantages, and then turn around and try to have a different claim scope now that we are in litigation.

Patent claims are not a nose of wax. And the law has been long clear that the scope of a claim in prosecution is the scope of the claim in litigation.

Just one other point, sorry.

They make the point that as you lower estrogen cycle control generally declines. And that is true. But opposing counsel noted that that is all else equal. If you keep everything the same, and you lower estrogen, then the result would have been that cycle control would be worse. If you made other changes, that categorical rule may or may not have applied. It probably would have applied, but possibly not. It wouldn't have been scientifically impossible. And they didn't say that it was scientifically impossible. They said that their regimen outperformed the prior art that they described in their patent, and they said that they had better cycle control, and the reason that they had better cycle control is that they didn't just hold the prior art constant and lower estrogen dose. They introduced a different administration scheme that they said allowed them to achieve unexpected results. Innovation sometimes has unexpected results.

The final argument that I mentioned before is -- while we are on the subject, I just wanted to, I think this is a good place to address the argument.

There are a number of arguments that they have made that you couldn't test, it would be impossible to know whether this would be better than these other patents. Well, certainly, they had a way of doing it. How would you know whether you were better than the prior art unless you tested it? And certainly, there would be a way to do that. We are not saying that you would just eyeball these and ask whether you were better or not. You would test the regimens. You would test embodiments of the patent. And that's how you would know.

A brief point, these are distinct terms. Each is a requirement. These cover distinct concepts. You can have high contraceptive reliability, for example, but not avoid undesirable side effects. This would be very different language if some of these were not present. And they are connected with conjunctive terms. Each is a requirement.

It's not clear what Bayer is proposing, if this is one term, how an infringement analysis would proceed. Is each of these going to have to be satisfied for an infringement analysis? It is unclear what they are even proposing with that.

This idea that this is all one combination of characteristics doesn't tell us, if each of these does not require superior performance, it doesn't tell us how good each of these characteristics needs to be. It is easy to say we came up with a combination, we balanced things. It is another thing to point out exactly how that balance worked. There is no discussion of that in the intrinsic evidence. It is, as we pointed out, an unabashed, unequivocal statement of superiority.

I am now ready to talk about the individual claim terms. Let's start with "high contraceptive reliability."

Consistent with the standard of superiority that we have been talking about, when we are thinking about these vague terms and how to come up with a more precise standard, Warner Chilcott is proposing that this term be construed to mean contraceptive efficacy measured using the Pearl Index, greater than that of each and every prior art oral contraceptive identified in the '940 patent's specification.

Bayer, on the other hand, simply repeats the disputed language, which is not helpful, and then they tack on this "as compared to" language, as compared to a population of healthy women not using hormonal birth control, that is not anywhere in the intrinsic evidence. We will talk about that later. But it is not clear what that

even means or how that would advance the infringement analysis.

The real issue before Your Honor is what does "high" mean. How high does this contraceptive reliability have to be? This is an imprecise term, it is a term of degree, so different people could mean different things when they talk about what high contraceptive reliability means.

Just in lay terms, someone might call a basketball hoop high, another person might call a mountain high. It doesn't mean they are the same height.

And high requires a comparison to some standard. How high? High as compared to what? Is the tallest building in Wilmington high? If our standard is a three-story townhouse, yes. But if it is the Empire State Building, no.

This is precisely why under the Datamize principle, we need to look at the intrinsic evidence for a standard. And that is where the prosecution history and standard come in.

I am just going to go through this a little bit more carefully for Your Honor.

So there was initially a rejection, an obviousness rejection Your Honor has heard about, based on the Ehrlich and Pasquale references. In response, the applicants amended their claims. The way that they amended

their claims to overcome that obviousness rejection was to add the underlined language here in the whereby clause. That incorporates this set of terms that we are talking about, including high contraceptive reliability and the other terms.

Then on Page 5 is where they explained what they were doing. They talk about the fact that these claims are obvious over the Ehrlich and Pasquale combination, briefly describe what those references disclose. Then they go on to talk about how their regimen contrasts with the deficiencies of the prior art multiphasic combination preparations discussed in the specification. And they talk about what those distinguishing characteristics are. One of those is high contraceptive reliability. High contraceptive reliability there is being used to mean a degree that contrasts a degree of reliability, that contrasts their regimen with the prior art.

What were the deficiencies?

Column 6 enumerates some of the deficiencies and explains how their regimen addresses the deficiencies. It lines up with these terms here.

In the last sentence, which opposing counsel looked at as well, they give an example of a couple of references that lacked these five results.

There is no suggestion in either of the

references -- there they are referring back to Ehrlich and Pasquale, and they are saying, there is no suggestion that you could get these results in those.

What is that saying? These results, 1, 2, 3, 4, 5, are lacking. Then they didn't stop there. They said there is no teaching in the cited prior art, all of it, whereby the low effective estrogen content and low total hormone content provides the five, the set of characteristics that we are talking about here, one of them being high contraceptive reliability.

They go on to say that their regimen provided in a low-dose regimen these characteristics for the first time. Each of these is a superior result. They supplied each of these. These are characteristics the prior art lacked.

And if there were any question, what did they say in their specification? They said that they had greater contraceptive reliability than all of them. What does high contraceptive reliability mean here? It means a standard that outperforms the prior art.

It was precisely this addition, this amendment, that allowed them to get the patent. That's how they distinguished.

What does Bayer say? They are not entirely clear. But they suggest that combination of oral contraceptives, all of them have this. This is from the Dr.

Shulman declaration. But there are other suggestions in their briefing. What is wrong? Then they argue, also, that Ehrlich and Pasquale, which we were just talking about, have high contraceptive reliability. What is wrong with those arguments?

It is fundamentally inconsistent with the prosecution history.

If all oral contraceptives have high contraceptive reliability already, it would have made no sense for them to call this a superior result. All oral contraceptives would already have this. It wouldn't make sense to list it as a superior result.

What is happening here?

Essentially, Bayer is trying to rewrite the prosecution history to read out this superior result.

And the same thing goes for the whereby clause. If all oral contraceptives had this standard, it would have made no sense to include that as a distinguishing characteristic. Implicitly, all of them would have it. You wouldn't need to list that. It would be redundant.

And Bayer's argument that Ehrlich and Pasquale already had high contraceptive reliability is again inconsistent with the prosecution history.

We talked before about what this last sentence is saying. It is saying that there is no suggestion in

either of these references -- and I am talking there about the last sentence -- that these results, plural, this set of results that they referred to earlier, including high contraceptive reliability, no suggestion of those results.

Well, in saying that Ehrlich and Pasquale had this, they are again essentially rewriting the prosecution history to say, what would that prosecution have looked like if those had high contraceptive reliability under the standard? It would have been written to say, well, Ehrlich and Pasquale each had high contraceptive reliability. There is no --

THE COURT: I need to pause for a moment, please.

(Brief recess.)

THE COURT: Thank you. Sorry.

MR. SONNENSCHEIN: They wouldn't have written this the way they did if Ehrlich and Pasquale had. They would have written this to say, while Ehrlich and Pasquale each had high contraceptive reliability, there is no suggestion in either of these references that these other results -- these other results -- would have been present. They didn't say that.

It was a sweeping statement.

One argument that I will quickly pass over because they didn't raise it here, but they do hint at it in

their briefing, is that somehow Ehrlich and Pasquale can be distinguished on the basis of dose. But they are all low-dose regimens.

Let's talk about the Bayer construction. "High contraceptive reliability as compared to a population of healthy women not using hormonal birth control." What is the first problem with this?

This phrase is not present, is not suggested, in the intrinsic evidence. This is something that the lawyers have made up to distract from what the real comparison was, which was the prior art here. And there is no acknowledgment in this construction of the fundamental fact that this term was added to overcome an obviousness rejection and to distinguish this as superior.

Under the way that they approach it, one would never know about this prosecution history, that this term has to mean better than the prior art at least in some way.

And who is this population of women that they are proposing? They just tell us, a healthy population of women not using hormonal birth control. They don't tell us if they are using any birth control, and if so, what kind? Clearly, there is a difference in pregnancy risk for a group of women who are using some form of contraception as opposed to no contraception at all.

And there is no discussion here about other

characteristics. For example, what are the ages? What is the fertility of these women? How sexually active are they? These all affect the question of what that comparison would entail.

More fundamentally, there is no objective standard here. Compare it a population of women, okay, let's do that. How? How reliable does this have to be if we compare it to a population of women? This just does not answer the question.

The best that they can do is, in their reply brief, just say that an oral contraceptive has high contraceptive reliability when the pregnancy rate is low when using the contraceptive when compared to healthy women who are not using hormonal contraception.

That just begs the question, how low? What is the cutoff?

Just to note this point, which Your Honor is aware of, but ordinary meaning won't cut it when ordinary meaning doesn't resolve disputes about claim scope.

So to the extent this has an ordinary meaning, it's not enough. We need greater clarity. The standard here, if there is any, is the prior art. And if that is not the standard, then there is no standard, and we are dealing with an indefinite claim.

The last part of this is our construction

measured using the Pearl Index. We need to have some way of measuring the contraceptive reliability. So how do we do that? We use the standard at the time of the invention. And the standard at the time of the invention was the Pearl Index. If we don't use that, what measure do we use? And Bayer doesn't propose. They just say, this can't work, but they don't tell us which one does. So how would we even conduct the infringement analysis when we get down the road?

The Honeywell case that we cite makes the point that when you have multiple potential tests and they could potentially generate different conclusions about infringement, that's indefinite. We need, for an objective standard, we need a standard. We are proposing the Pearl Index. Is it perfect? It's not perfect. But would that have been the standard? It would have been the standard.

What is Bayer's primary problem with it? They say you can't compare two contraceptives using the Pearl Index. The prior art did compare using the Pearl Index. Just very briefly, two examples in the extrinsic evidence, The Akfhlund study, this compared the reliability of two regimens using the Pearl Index. The Corson study used the Pearl Index to compare multiple regimens.

The problem that Bayer points to is the idea that if you use the Pearl Index but you don't compare different oral contraceptives over the same length of time,

then that can create distortions. We are not proposing that these be compared over different lengths of time. One would compare over the same length of time. And one would do it in a clinical trial.

We are not saying you wouldn't test it. You would test it.

Let's turn to the next term. "Low instance of follicular development." This is in approach fundamentally the same as "high contraceptive reliability." We have a term, "low," a term of degree. We need an objective standard. What is the objective standard? We have looked to the intrinsic evidence. What is the only objective standard that is suggested? Again, it's the prior art, better than the prior art.

What does low mean in this context? If it means anything, it means better than the prior art.

Consistent with that approach, Warner Chilcott proposes: A lesser incidence of follicular development than the incidence with each of the prior art regimens identified in the '940 patent.

Bayer, in approach, again, they use the same fundamental approach, repeat the language and tack on "as compared to" language.

Very briefly, I just wanted to talk about "follicular development" and "incidence" before we get to

"low."

What is follicular development? Well, women become pregnant by producing an egg. In that event -- the fancy term for it is ovulation. When the woman produces the egg, it travels through the fallopian tube. And if sperm is there to fertilize the egg, conception will occur. There will be implantation of that fertilized egg in the wall of the uterus and a pregnancy will result.

How is an egg produced?

Tiny structures in the ovary called follicles grow to the point where one gets so big that it bursts and an egg is released. That is what this is showing, that process of growth.

This is another illustration of that phenomenon.

As Your Honor can see, follicular development is a process. It occurs along a continuum. So at some point, when we are talking about what is an incident of follicular development, there is a line-drawing problem. How far along this continuum does that follicle need to have grown for there to be an incident?

What does the patent mean by incidence of follicular development? It's talking about frequency. How often is this occurring? And we see that, for example, in Column 6, Lines 9 through 19, where they are talking about how their regimen compares to the prior art. And they are

saying that there is a lower frequency of follicular development. What do they mean by that? A lower incidence.

How could one go about figuring out what an incidence of follicular development is? We just wanted to illustrate one possible way so that Your Honor has the benefit of this. This explanation is not laid out in the '940 patent but it is laid out in the '129, which is cited in the patent.

So in this Figure 2, Your Honor will see that what these inventors did was to say -- to look at the percentage of females with follicular maturation -- by that presumably they meant follicular development, that is a synonym -- and in terms of talking about incidence, they are just talking about how many women, what percentage of women had this.

In this example, they are comparing the percentage of women or the incidence of women on two different oral contraceptives, a 21-day and a 23-day. What was the incidence here? For the 21-day in Cycle 1 it was 20 percent. For the 23-day, it was ten percent.

And then Your Honor can see different numbers for the different cycles.

And if Your Honor recalls, this is a continuum of growth, how far along are we to determine at what point there is an incident. In this instance, they defined what

follicular development was. They said greater than 13 millimeters. They gave a standard. There is no standard in the '940 patent.

But in any event, the fundamental question comes down to what is meant by low. And at this point the analysis parallels what we talked about with high. We need an objective standard, and we look to the intrinsic evidence, the prosecution history. I can go through this again. But low incidence was added to overcome an obviousness rejection. It was one of the superior results, and so forth.

And if there is any question of what they were saying -- okay. What's wrong with the Bayer construction? Well, it's the same fundamental problems that we talked about before. No basis for adding this. Fundamental lack of recognition about the context in which this term was added, superiority, they meant superiority. Not comparing it to a population of women that are not using hormonal birth control.

The only flaw that I wanted to focus on a little bit more was the fact that this is not a helpful standard. It is an ambiguous standard.

To start, while Bayer proposes in its construction -- let me just back up -- they are talking about low incidence as compared to a population of healthy

women not using hormonal birth control. In their brief, they change that standard. And now, rather than as compared to a population of women not using hormonal birth control, they are talking about the normal menstrual cycle. You see that here at Page 15 of their opening brief.

What is this normal menstrual cycle? Is this an eight-year-old's menstrual cycle? Is this a 30-year-old's? That would presumably affect the analysis.

What we are assuming is by normal they mean ideal. And by ideal we are talking about a cycle in which ovulation occurred. As we looked at before, for ovulation to occur, you need to have follicular development, however that is defined, because there is no egg if the follicle doesn't develop. We are assuming a hundred percent. It doesn't really matter.

The fundamental problem of this is, we don't know, under their construction, what a low incidence of follicular development is. How does it have to compare?

And in this demonstrative, Your Honor sees hypothetical oral contraceptives A through D, and we are comparing it to the normal menstrual cycle as they have done in their brief.

How much lower does the incidence of follicular development have to be on these other oral contraceptives to be said to have a low incidence? Is it any increment, or is

it an increment like with C, or is it some other increment?

Where do we draw the line?

To simply say compare it to a normal menstrual cycle doesn't answer the fundamental question: What does low mean? There is no standard.

Are we saying we need a precise numerical percentage? No. But we do need an objective standard.

Bayer suggests in its brief that there would have been a known standard, a known default standard in the art, someone would just know what this cutoff was. They cite these four examples of extrinsic evidence. Not one of them even mentions this phrase "incidence of follicular development." And none of them identified that threshold.

Where do you draw the line that would tell you what the scope of the claim is? That would tell you how you would conduct an infringement analysis? How do I know if I am in or I am out?

There needs to be an objective way to assess that.

They point at Dr. Shulman's testimony that people can make an assessment of whether it is low based on the studied population, the regimen, and the amount of ovarian activity over time. What does that mean? That is not an objective standard. Just throwing out a bunch of factors that someone could consider isn't getting the job

done.

And this clinical assessment that he talks about is nowhere present in this '940 patent.

Dr. Simon notes that absent more specificity, the dividing line between an oral contraceptive with low and one that did not have low incidence wouldn't have been clear.

Now let's talk about the next term, "satisfactory cycle control."

Again, fundamentally, the approach is the same. We have this term satisfactory. We need an objective standard to give some definition to this otherwise amorphous concept. And the standard suggested in the intrinsic evidence is superiority. Then the only question is what does better mean? What does superior mean? We look to a discussion of what cycle control means.

What does cycle control mean? What we have up here is just a diagram of this 21/7 regimen that opposing counsel discussed. And as opposing counsel noted, traditionally, in the seven final days of a 28-day cycle, women would bleed because of the withdrawal of hormones. So they would expect bleeding during this period, this interval. But they would not during the other days, days in which a combination of hormones was administered.

So the fundamental concept when we are talking

about cycle control is how well is this contraceptive avoiding this unscheduled bleeding. And there are different ways of characterizing what that is. One term for it used in the '940 patent is intracyclic menstrual bleeding.

And the patent defines cycle control as incidence of intracyclic menstrual bleeding. In other words, what is the frequency or the incidence of this unscheduled bleeding? The lesser the frequency, the better the cycle control.

Bayer argues that for purposes of the '940 patent, cycle control includes a phenomenon called amenorrhea. But if Your Honor looks at Paragraph 6 of the '940 patent, at Column 6, Lines 39 through 40, they are specifically distinguishing cycle control from this phenomenon called amenorrhea.

So for purposes of this patent, what we are talking about for cycle control, which would ordinarily encompass a wide variety of different measures and characteristics, is incidence of the bleeding. So then the question is, what does satisfactory incidence mean? It's the same analysis that we went through before.

Bayer's proposal, satisfactory cycle control, parallels its other constructions of these other terms, same problems. No basis for this "as compared to" language, and no acknowledgment of the prosecution history and the

fundamental fact that this term was added to distinguish the claimed regimen from the prior art and that that has a clear effect on the meaning.

What do they argue? Well, I just wanted to highlight that there is this standard that they are proposing is also ambiguous. What is the problem with it? Well, one of the problems is, where is the line? We need to know what the line is, whether we are in or we are out. So where do you draw that line to know where unsatisfactory begins and where it ends?

The best that Bayer can do is to cite extrinsic evidence. And it is highlighted here on the right. And we have done our best to estimate overall bleeding rates based on these articles. And they say, well, these people were able to come up with assessments, so, therefore, of course, people know what this means. This is clear. That seems to be the argument.

What is the problem with that?

Well, again, it doesn't tell us what the boundary line is. I wanted to give just an analogy here. Let's imagine that Congress wanted to impose a tax on the rich. That phrase by itself would not adequately tell us who all was affected and who was not. We would need a more precise standard. The fact that we know that Bill Gates is rich, he is clearly on one side of the line and everyone

would agree with that. And not rich, the homeless person is clearly not, doesn't answer the question about what the dividing line is. And the Nautilus decision by the Supreme Court last month makes this point, you can't have a zone of uncertainty. You need more clarity.

So to just say satisfactory and point to some examples isn't enough.

And, very quickly, this concept, certainly in some instances people absolutely had ideas about cycle control of particular regimens. But in terms of an overall standardization of methods, this 2007 article by this group of thought leaders notes that there wasn't even a standardization of methods over ten years after as to how you would analyze this cycle control data.

There was no clear delineation of some accepted standard. And the Weisberg chapter that Bayer cites in its brief as extrinsic evidence makes the point that different women respond differently to bleeding. Adolescents will respond differently. So there is no single line for satisfactory. People will have different ideas about that.

So that's our summary of our construction.

Let's move to "reliable avoidance of intracyclic menstrual bleeding."

We are proposing the same construction. The reason we are doing that is, as I have discussed before,

cycle control is defined by the patent in terms of incidence of intracyclic menstrual bleeding. And the standard for reliable avoidance is again one of superiority.

So it is the same.

"Reliable avoidance of undesirable side effects," last term in this set, again, it's the same analytic approach. We need a standard. The only thing that I want to focus on is, again, some additional flaws and additional questions raised by the Bayer construction that makes their construction only raise questions rather than resolve them.

Let me just back up.

To compare this reliable avoidance to a population of healthy women not using hormonal birth control is nonsensical because women who don't use contraceptives won't have side effects. So when we do a comparison and we say, as compared to a population not using hormonal birth control, we are really comparing women who have -- assuming they are not using any contraception -- women who have no side effects compared to women who do.

Again, we have the same line-drawing problem with their construction. At what point does one cross the line from reliably avoiding a side effect to no longer reliably? What is our standard? What is our objective standard?

This doesn't offer it.

Bayer points out that we need to look to characteristics in the underlying population as a control. That is not evidence from the construction on its face. They just say that. But even indulging that, the same fundamental problem arises.

So in this example, we are comparing these oral contraceptives, these hypothetical contraceptives on the right to this population of women not using hormonal birth control. And we are assuming that the incidence is 15 percent. That just raises the same question: How much greater can this condition be for an oral contraceptive to still be said to reliably avoid a side effect?

There is another fundamental problem with their construction. There are several undesirable side effects for oral contraceptives. And they range from minor, relatively minor to life-threatening. Nausea, not a good thing but it won't kill people. Stroke can.

So what is the standard for each of these side effects? Is the increment over the baseline going to be the same for a side effect like stroke as opposed to a side effect like bloating? Again, they don't answer that.

There are a whole slew of questions that their construction does not answer but instead raises. That is additional reason to reject it.

I wanted to talk about the final two terms. I wanted to talk about "between these two hormone components."

On this, the only reason that we are proposing this term for construction is the fact that Bayer has accused the Warner Chilcott Lo Loestrin product of literal infringement. The only way that that allegation could be maintained in good faith is if there is a dispute about what this language means. And under the 02 Micro case, when there is a dispute about ordinary meaning, there needs to be a resolution.

So what is it that we are proposing? That between these two hormonal components means "immediately after a hormone component containing a combination of estrogen and progestin, and immediately before a hormone component containing estrogen only."

Bayer proposes, "after the first hormone component and before the second."

The fundamental difference between these constructions is that Warner Chilcott includes this immediately term while Bayer does not. And it is that absence that is the fundamental difference and the fundamental reason why the Court should adopt the construction that we are proposing.

I am not going to belabor this, but what we have on the left is a depiction which actually comes from one of

Bayer's prior briefs, a depiction of this claim language. And this is one embodiment. And we have added color to it. But fundamentally, this is a graphic illustration of an embodiment of Claim 1. What we have between these two hormone components are two or one blank pill days. That's what we have here. And then we have a first hormone component, in blue, and a second hormone component in orange.

And the claim directs and advises that the first has a combination of estrogen and progestin, and that it's provided for 23 or 24 days. So that's what we have in blue. And in this instance it's 24 days.

And then the second hormone component is essentially an estrogen preparation.

As Your Honor noted with Your Honor's question, this does amount to the same thing as estrogen only.

So the question here is what does "between these two hormone components" mean. And to give precision and avoid confusion about claim scope, we would ask Your Honor to adopt the Warner Chilcott construction: immediately after a hormone component containing a combination of estrogen and progestin, and immediately before a hormone component containing estrogen only.

Why is it that we want this term to be construed? Well, I mentioned before, we have the

Lo Loestrin product. The Lo Loestrin product does not provide placebo tablets between the two hormone components. Yet Bayer is alleging literal infringement. How is it that they propose to do that? Well, apparently, they want to extend the inquiry into multiple cycles. And by using their imprecise definition, they will try to confuse a jury into saying that these placebo tablets are between the first hormone component and the second.

What will they argue? Under their very imprecise construction, all you have to do is be after. It doesn't matter where or how far after. You just have to be after. And all you need to do to be before the second is come at some point before, even if not immediately before.

What is wrong with that? Well, the claim requires that these first and second hormone components be in a single packaging unit, not multiple. And the Bayer construction is trying to read that out to say we can look at multiple sites.

So we would ask that the Court adopt our construction, "immediately after a hormone component containing estrogen and progestin, and immediately before."

The last term, "effective estrogen content." Warner Chilcott proposes "a daily dose of estrogen, equivalent to at least 15 micrograms of ethinyl estradiol in the combination tablets, and equivalent to at least two

micrograms of ethinyl estradiol in the estrogen-only tablets."

Bayer is proposing "no more than 40 micrograms."

In principle, what is this "effective" term doing? What function is it serving in the claim?

Effective is a limit on how low one can go. As one lowers estrogen, you can impair contraceptive efficacy. So the question is, how low does that have to be? What is the boundary, what is the minimum bound?

We would note that, as opposing counsel noted, the object of the invention is to make available a combination preparation with an estrogen content that is as low as possible in each individual dosage unit. What does that mean in terms of what should be preferred if something lower than 15 would be effective? It would mean that they would preferred something less than 15 micrograms. That's what a person of ordinary skill in the art would understand in that first hormone component.

So we are proposing "equivalent to at least 15 micrograms of ethinyl estradiol in combination tablets." The patent contains a different range, down to two micrograms with the second hormone component. We are proposing for that "equivalent to at least two micrograms of ethinyl estradiol in the estrogen-only tablets."

That may seem a bit anomalous, that you would

have two different amounts, but Your Honor should keep in mind that what we have here is the 21/7 regimen that I talked about before. This is the traditional regimen. All that these estrogen-only, the estrogen-only tablets are doing is providing some amount of estrogen where previously no estrogen was provided.

So to give something as low as two wouldn't be problematic for efficacy. But when you are talking about the combination tablets, this is the bulk of the regimen. And now we are talking about 24 days. But historically, 21 days had much higher estrogen doses. The '940 patent notes that at the time 20 was the lowest in a marketed product.

So estrogen dose would need to be higher here.

Let's talk about the Bayer construction. They say no more than 40 micrograms. What are the problems with that? There is no statement in the patent that if you raise estrogen above 40 micrograms there is going to be a problem with effectiveness. It doesn't say that. And they themselves note that 50-microgram products were sold and marketed.

They are importing a limitation from the specification. They are treating a preferred dose of 40. They are doing what they accuse Warner Chilcott of doing, importing a limitation.

We would say that the difference here is that

the Phillips case notes that when a preferred embodiment is coextensive, as we think that it is, with the 15-microgram dose, that the Court should adopt that.

There is no indication here that they intended 40 micrograms to be an upper limit.

Then the other point about it is, as we talked about before, effective estrogen content, the function of that in the claims is to provide some minimum. And to just say you can't go above 40 essentially reads out the minimum.

The final point that I just wanted to make about claim differentiation, we don't think that that has any merit. I think they pointed to Claim 1 and Claim 4 as being the same under our construction. It's not, among other reasons, because Claim 4 has a narrower set of estrogens and progestins than Claim 1.

That is my presentation. We appreciate Your Honor's time.

THE COURT: Thank you, counsel.

Brief reply.

MR. FORD: Yes.

THE COURT: I have the slides, counsel. I can do without that.

MR. FORD: It's just to orient.

THE COURT: I am pretty well oriented.

MR. FORD: Point taken, Your Honor.

First, does your Court have any questions?

THE COURT: If I did, I would ask them.

MR. FORD: I appreciate that.

Your Honor, very briefly.

The prosecution history itself, with respect to the reading of these two sentences in which it's stated that Bayer's patent had achieved for the first time each and every one of these results, when read in the context of the paragraph, it is stating that Bayer has put together a regimen using a low effective estrogen content, low total hormonal content that achieves the effects that follow.

The prior art, the Ehrlich and the Pasquale reference, and Luchnit reference all state that the object of those inventions is high contraceptive reliability. That was known at the time. And it would not have made sense for Bayer to claim, in a rejection over patents that claim high contraceptive reliability, that they have achieved high contraceptive reliability for the first time or superior contraceptive reliability for the first time.

Instead, the effects themselves are again part of the contraceptive regimen that is the profile that is set forth. And it's a balancing act that must be achieved.

In reading the prosecution history, Bayer has obtained the patent by saying that these results, meaning the use of a low effective estrogen content, low total

hormone content, whereby these characteristics are attendant, is what differentiates it from the prior art, not that each individual circumstance is improved over the prior art.

I can say for the record that we are not seeking literal infringement. So for purposes of the "between the two hormone components," we didn't think there was much of a dispute. But that term I don't think needs much construction there.

Unless the Court has any other questions, I will end there.

THE COURT: I guess the fact that you are not any longer seeking a finding of literal infringement will be welcome news to the other side, and inform at least to some degree the proceedings, pretrial proceedings.

Yes, counsel?

MR. SONNENSCHEIN: The only thing that I would clarify -- there is also an interference claim. That requires the Court to ask whether each of the claims would anticipate each other. So the construction would still matter. I guess the question is why they are not willing to just agree to our construction. It is just effectuating the plain and ordinary meaning.

THE COURT: Is there a reason?

MR. FORD: If it will facilitate things, we can

adopt that construction. That's fine.

MR. SONNENSCHEIN: Wonderful. And thank you.

We have nothing else.

THE COURT: Everything else is going okay?

All right. Thank you, counsel.

(Counsel respond "Thank you, Your Honor.")

(Court recessed at 11:22 a.m.)

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Reporter: Kevin Maurer